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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,349	10/07/2003	David H. Walker	D6152CIP2/D1/D	5963
7	590 03/24/2005		EXAM	INER
David L. Park	er & JAWORSKI L.L.P.		MINNIFIEL	D, NITA M
600 Congress A			ART UNIT	PAPER NUMBER
Suite 2400			1645	
Austin, TX 7	8701		DATE MAILED: 03/24/2005	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/680,349	WALKER ET AL.
Office Action Summary	Examiner	Art Unit
	N. M. Minnifield	1645
The MAILING DATE of this communication app		orrespondence address
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailing - earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tim y within the statutory minimum of thirty (30) days vill apply and will expire SIX (6) MONTHS from t , cause the application to become ABANDONED	ely filed will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1)⊠ Responsive to communication(s) filed on <u>05 Ja</u>	anuary 2005.	
	action is non-final.	
3) Since this application is in condition for alloward closed in accordance with the practice under E		
Disposition of Claims		
4) ⊠ Claim(s) 1 and 2 is/are pending in the applicate 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1 and 2 is/are rejected.  7) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to restriction and/or	wn from consideration.	
Application Papers		
9) The specification is objected to by the Examine 10) The drawing(s) filed on <u>07 October 2003</u> is/are.  Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	: a)⊠ accepted or b)⊡ objected drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Application rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892) L'Shetto 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/5/05. 3 Sheets	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	(PTO-413) te atent Application (PTO-152)

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## **DETAILED ACTION**

1. Applicant's election of species of SEQ ID NO: 41 and 42 in the reply filed on January 5, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

- 2. Applicants' amendment filed January 5, 2005 is acknowledged and has been entered. Claims 1 and 2 have been amended.
- 3. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "an amino acid sequence". Does Applicant intend for this phrase to define the entire amino acid sequence of SEQ ID NO: 2 or a fragment of the amino acid sequence of SEQ ID NO: 2?
- 4. The disclosure is objected to because of the following informalities: the continuity data should be updated on page 1 of the specification. Appropriate correction is required.
- 5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Art Unit: 1645

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 6. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).
- 7. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Rikihisa et al (6,544,517).

Please note that the effective filing date for the pending claims is September 12, 2000, which is the date the full amino acid sequence of SEQ ID NO: 2 was first disclosed. SEQ ID NO: 2 was first disclosed in 09/660,587 filed September 12, 2000.

Rikihisa et al discloses the claimed amino acid and nucleic acid sequences as set forth in claimed SEQ ID NO: 42 and 41 respectively. SEQ ID NO: 48 and 47 as the same as Applicants' SEQ ID NO: 42 and 47 respectively (see sequence listing in issued patent).

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8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Rikihisa et al (WO 99/13720), Ohashi et al Infection and Immunity, 1998 or Reddy et al BBRC, 1998.

Rikihisa et al (WO 98/13720), for example, discloses claimed an amino acid sequence of SEQ ID NO: 42. The prior art discloses a 82% sequence match with the claimed SEQ ID NO: 42 (claim 12 and figure 4B). See sequence search result printouts attached.

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohashi et al J. Clinical Microbiology 1998.

Ohashi et al discloses the claimed amino acid and nucleic acid sequences as set forth in claimed SEQ ID NO: 42 and 41 respectively, please see attached sequence search result printout.

10. Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 2, as written, do not sufficiently distinguish over nucleic acids, and proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303,206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught and enabled in the specification. See MPEP 2105.

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11. No claims are allowed.

- 12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-A197 (toll-free).

Art Unit 1645

**NMM** 

March 21, 2005

GenCore version 5.1.6 Copyright (c) 1993 - 2005 Compugen Ltd.

OM protein - protein search, using sw model

Run on: February 17, 2005, 16:47:35; Search time 178 Seconds (without alignments) 805.518 Million cell updates/sec

Title: Perfect score: Sequence: US-10-680-349-42 1462

Scoring table: BLOSUM62
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Searched: 1612378 seqs, 512079187 residues

1612378

Total number of hits satisfying chosen parameters:

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Database : UniProt\_03:\*
1: uniprot\_sprot:\*
2: uniprot\_trembl:\* Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

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## SUMMARIES

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## ALIGNMENTS

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"Trainscriptional Analysis of p30 Major Outer Membrane Protein Genes of Ebrlichia canis in Naturally Infected Ticks and Sequence Analysis of p30-10 of E. canis from Diverse Geographic Regions.";
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                                                                                                    MEDLINE=22384137; PubMed=12496165; DOI=10.1128/IAI.71.1.187-195.2003; Cheng C., Paddock C.D., Ganta R.R.; Molecular heterogeneity of the chaffeensis isolates determined by sequence analysis of the 28-kilodalton outer membrane protein generand other regions of the genome."; Infect. Immun. 71:187-195(2003).
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"Nolecular heterogeneity of Ehrlichia chaffeensis isolates determined

y sequence analysis of the 28-kilodalton outer membrane protein genes

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Infect. Immun. 71:187-195(2003).
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STRAIN=Arkansas;
MEDLINE=21153566; PubMed=11254561;
                                                   Ohashi N. Zhi N. Zhang Y., Rikihisa Y.; "Immunodominant major outer membrane proteins are encoded by a polymorphic multigene family. Infect. Immun. 66:132-139(1998).
                                                                                         MEDLINE=98084465; PubMed=9423849; Ohashi N., Zhi N., Zhang Y., Rikihisa Y.;
                                                                                                                                                                                                                        "Molecular heterogeneity of Ehrlichia chaffeensis isolates
by sequence analysis of the 28-kilodalton outer membrane pa
and other regions of the genome.";
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MEDLINE=22384137; PubMed=12496165;
Cheng C., Paddock C.D., Ganta R.R.;
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Alleman A.R.;
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the tribe Ehrlichiae.";
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  ELEAAYQQFNFKNTDNNDTDNGEYYKHFALSRKDAMEDQQYVVLKNDGITFMSLMVNTCY
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          EETPINGTNSLTKKVFGLKKOGDITKKDDFTRVAPGIDFQNNLISGFSGSIGYSMDGPRI
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                                                                                                                                                        Paddock C.D., (FEB-2002) to
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    (TrEMBLrel. 08, Created)
(TrEMBLrel. 23, Last sequence update)
(TrEMBLrel. 27, Last annotation update)
membrane protein gene 14 (Major outer m
                                                                                                                                                                                                                                                                                                                                                                     Sulsona
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                                                                                                                                                                                                            ons of the genome.";
71:187-195(2003).
                                                                                                                                                                                                                                                                                                                                                                  PubMed=9647746; DOI=10.1006/bbrc.1998.8844; na C.R., Barbet A.F., Mahan S.M., Burridge M
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 31042 MW;
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                                                                                                                                                        Ganta R.R.;
the EMBL/GenBank/DDBJ databases
                                                                                                                                                                                                                                                                                                                                                                                                                                                 Alphaproteobacteria;
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Pred. No. 2.96
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RESULT 7

Q9R443

LD Q9R443

AC Q9R4

AC Q9R4

DT 01-W

DT 05-C

OS COWN

OC Baci

OC Ana

OX NCB

RN [1]

RR [2]

RR [2]

RR [3]

RR [1]

RR [3]

RR [1]

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RR [5]
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Best Local Similarity
Matches 215; Conserv
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Best Local Similarity
Matches 225; Conser
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01-MAY-2000
01-MAY-2000
                                                                                                                                                                                                  SEQUENCE FROM N.A.

MEDLINE-99216274; PubMed=10198207; DOI=10.1006/bbrc.1999.0459;
Sulsona C.R., Mahan S.M., Barbet A.F.;
Sulsona Gran, Mahan S.M., Barbet A.F.;
"The map1 gene of Cowdria ruminantium is a member of a multigene family containing both conserved and variable genes.";
Biochem. Biophys. Res. Commun. 257:300-305(1999).
EMBL; AF125279; AAD26353.1; -.
EMBL; AF125274; AAD26349.1; -.
EMBL; AF125277; AAD26349.1; -.
EMBL; AF125277; AAD26349.1; -.
EMBL; AF125278; AAD26351.1; -.
                                                                                                                                                                                                                                                                                                                                                                                                                                                                    01-MAY-2000 (TrEMBLrel. 13, Created)
01-MAY-2000 (TrEMBLrel. 13, Last sequence update)
05-JUL-2004 (TrEMBLrel. 27, Last annotation update)
Major antigenic protein 1 like protein.
Cowdris ruminantium.
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RMBL; AP479833; AAA012929:1; -.

RMBL; U72291; AAC02936:1; -.

RMBL; AP479834; AAC02936:1; -.

INTERPOOT IPRO02566; Surface Ag_map4.

Pfam; PP01617; Surface Ag_2; 1.

SEQUENCE 283 AA; 31017 MW; DCBCF6521
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Ohashi N., Rikihisa Y., Unver A.;
"Analysis of transcriptionally active gene clusters of major outer
                                                                                                                                                                                                                                                                                                                                                                                                                                 Bacteria; Proteobacteria; Alphaproteobacteria; Rickettsiales;
Anaplasmataceae; Ehrlichia.
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      Q9R443
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                                                                                                                                                                                                                                                                                                                                                                                                           NCBI_TaxID=779;
                                                                                                                                             InterPro; IPR002566; Surface Ag_msp4.
Pfam; PF01617; Surface Ag_2; 1.
SEQUENCE 282 AA; 31040 MW; OCB3C6
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   241
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            178 DITAEGVSFVPYACAGIGADLITIFKDLNLKFAYQGKIGISYPITPEVSAFIGGYYHGVI 237
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          1 MNYKKILVRSALISLMSILPYQSFADPVGSR---TNDNKEGFYISAKYNPSISHFRKFSA 57
                   MYKKILVRSALISLMSILPYQSFADPVGSRT--NDN-KEGFYISAKYNPSISHFRKFSA 57
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MYKKILVRSALISLMSFLÞYQSFAEÞVSSNNIGNENAKEGFYISAKYNÞSIÞHFRKFSA
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                                                                      Conservative
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                                                                                        76.9%;
                                                                    Score 1124; DB 2;
Pred. No. 8.7e-82;
26; Mismatches 38;
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                                                                                                                                                 OCB3C655775CBC90 CRC64;
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AUTHORS
TITLE
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Sequence 47
AR303107
AR303107.1
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1 (bases 1 to 843)
Rikihisa, Y. and Ohashi, N.
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                    ATTAGTGCAAAGTACAATCCAAGTATATCACACTTTAGAAAATTCTCTGCTGAAGAAACT
                                          TATCAGTCTTTTGCAGATCCTGTAGGTTCAAGAACTAATGATAACAAAGAAGCTTCTAC
                                                       TATCAGTCTTTTGCAGATCCTGTAGGTTCAAGAACTAATGATAACAAAGAAGGCTTCTAC
                                                                                    ATGAATTATAAGAAAATTCTAGTAAGAAGCGCGTTAATCTCATTAATGTCAATCTTACCA
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                                                                                                                                                                                                                                      membrane protein of Ehrlichia canis and Ehrlichia chaffeensist: US 6544517-A 47 08-APR-2003;
                                                                                                                                                                                               /organism="unknown"
/mol_type="genomic
                                                                                                                                                                                                                                 Location/Qualifiers
                                                                                                                                                                                                                                                                                                                                                           from patent
                                                                                                                                    100.0%; Score 840; DB 6; 100.0%; Pred. No. 3.1e-140; tive 0; Mismatches 0;
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Relek,S., Greene,R. and Rikihisa,Y.
Direct Submission
Submitted (12-JUL-2002) Veterinary Biosciences, Of
University, 1900 Coffey Road, Columbus, OH 43210,
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Transcriptional Analysis of p30 Major Outer Membrane Protein Genes of Enriichia camis in Naturally Infected Ticks and Sequence Analysis of p30-10 of E. canis from Diverse Geographic Regions J. Clin. Microbiol. 41 (2), 886-888 (2003)
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	3 '
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Location/Qualifiers	PEATURES BOU
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	PUBMED REFERENCE AUTHORS
	JOURNAL MEDLINE
Anaplasmataceae; Ehrlichia.  1 (bases 1 to 906)  Pelek, S., Greene, R. and Rikihisa, Y.  Transcriptional Analysis of p30 Major Outer Membrane P.  Of Ehrlichia canis in Naturally Infected Ticks and Sequence of Ehrlichia Canis in Naturally infected Ticks and Sequence of Ehrlichia Canis in Naturally infected Ticks and Sequence of Canis of Naturally in From Diverse Geographic Analysis of Naturally in From Diverse Geographic Canis of Naturally in Programming Canis of Natural Progr	REFERENCE AUTHORS TITLE
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781 GCTTCAGTAACTCTTGACGTTGGATACTTTGGCGGAGAAATTGGGATCAGGTTCACCTTC 840	Ś
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REFERENCE AUTHORS TITLE ACCESSION VERSION KEYWORDS SOURCE ORGANISM

RESULT 7 AF324792

BCT 11-APR-2001

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LOCUS DEFINITION AF324792 6913 bp DNA linear BCT 11-APR-2 Ehrlichia canis phosphoribosylaminoimidazole carboxylase (purK) gene, complete cds; major outer membrane protein gene cluster 2, complete sequence; and u6 gene, partial cds.

AF324792 1 (bases 1 to 6913)
Ohashi.N., Unver,A., Zhi,N. and Rikihisa,Y.
Cloning and characterization of multigenes encoding the immunodominant 30-kilodalton major outer membrane proteins Ehrlichia canis and application of the recombinant protein gerodismant. Ehrlichia canis Ehrlichia canis Bacteria; Proteobacteria; Alphaproteobacteria; Rickettsiales; Anaplasmataceae; Ehrlichia. AF324792.1 GI:13591681 for

REFERENCE JOURNAL MEDLINE PUBMED serodiagnosis J. Clin. Microl 98371112 9705412 (bases 1 to 6913) 36 (9), 2671-2680 (1998)

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Ohashi,N., Rikihisa,Y. and Unver,A.
Direct Submission
Submitted (29-NOV-2000) Veterinary Biosciences, Ohio State
University, 1925 Coffey Rd., Columbus, OH 43210, USA
Location/Qualifiers
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    Ohashi,N., Rikihisa,Y. and Unver,A. Analysis of transcriptionally active gene clusters of major outer membrane protein multigene family in Ehrlichia canis and E.
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'strain="Oklahoma"
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100.0%; Score 840; DB 1; Lenyum 100.0%; Pred. No. 1.8e-140; Mismatches 0; Indels 6913;

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On Sep 18, 2000 this sequence version replaced g1:3769522.

Location/Qualifiers
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1 (bases 1 to 11329)
McBride, J.W., Yu, X. a
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4 (bases 1 to 11329)
McBride, Jw., Yu.X.J. and Walker,D.H.
Direct Submission
                                                                                                                                                                                                                                                                                                                                                                                                                 Submitted (07-AUG-1998) Pathology, University of Texas Medical Branch, 301 University Blvd., Galveston, TX 77555-0609, USA
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McBride, J.W., Yu, X.J. and Walker, D.H.
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McBride, J.W., Yu, X.J. and Walker, D.H.
A conserved, transcriptionally active
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Ehrlichia canis p28 multigene
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AF082744.2 GI:10181081
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